

### **REMARKS**

Claims 1-11 and 15-24 are pending in the case, of which claims 1 and 15 are independent. No claim is being amended. The Official Action mailed December 29, 2008 ("the Present Official Action") sets forth rejections of all claims based on either Luther U.S. Patent No. 4,964,854 ("Luther") alone or the combination of Crawford et al U.S. Patent No. 5,601,536 in view of Chang et al U.S. Patent No. 5,419,766 ("Crawford" and "Chang", respectively). In that regard, (a) claims 1-7, 9 and 15-23 stand rejected as anticipated over Luther, with remaining, dependent claims 8, 10, 11 and 24 being rejected for obviousness over Luther, and (b) all of the claims stand rejected for obviousness over the combination of Crawford in view of Chang. As set out below, it is submitted that these rejections should be withdrawn.<sup>1</sup>

#### **Luther U.S. Patent No. 4,964,854**

Claims 1-7, 9 and 15-23 are rejected as allegedly anticipated by Luther, with the remaining claims, dependent claims 8, 10, 11, and 24, being rejected as allegedly obvious thereover. However, Luther entirely lacks one of the claimed elements and so can neither anticipate nor render obvious the claimed invention. In particular, all of the pending claims specify a needle having "impeding means" (claim 1) or an "irregularity" (claim 15), with the impeding means or irregularity "defining a size larger than the shaft circumference and the gasket opening". In Luther, Examiner alleges that spring ferrule 60 is a "gasket". For reasons already previously set forth by Applicant in responses to prior Official Action, such a position is simply wrong. There is no technological basis for asserting that the spring ferrule is a gasket.

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<sup>1</sup> In order to streamline prosecution, the present Response focuses on certain distinctions which are submitted to be sufficient to overcome the rejections. Applicant does not waive any other argument available for patentability of any of the claims over the cited references or any other art, and reserves the right to present such arguments should that prove necessary.

In addition, and in any event, it is clear that there is no "impeding means" or "irregularity" of the needle in Luther to match up with the present claims. Instead, the needle of Luther has an inwardly annular groove defining a shoulder at 29 into which the leaflets 64 of spring ferrule seat to prevent proximal movement of the needle. That annular groove is clearly smaller than both the circumference of the shaft of the needle and of the alleged "gasket" of Luther. Indeed, it is noted that the Present Official Action nowhere references the claim requirement that the needle have impeding means or an irregularity "defining a size larger than the shaft circumference and the gasket opening" and fails to even mention that any such feature is disclosed or taught by Luther. And for good reason.

The annular groove of Luther creates a smaller area rather than a larger area, as compared to the either the needle shaft or the gasket opening, and thus is the opposite of what is claimed. Applicant submits that a reference surely cannot anticipate a claim to the opposite of that which the reference discloses. Nor is there basis to assert that it would have been obvious to re-create Luther so as to have the claimed opposite relationship. Rather, there is no expectation that Luther could work if the annular groove were replaced with something larger than the needle shaft and gasket opening.

Under the circumstances, there is no support for the rejections based on Luther and they should be withdrawn.

**Crawford et al U.S. Patent No. 5,601,536**  
**and Chang et al U.S. Patent No. 5,419,766**

All of the claims are also rejected as allegedly obvious over Crawford in view of Chang. For reasons set out below, these rejections are also traversed.<sup>2</sup>

Examiner first points to Figs. 11-14 of Crawford as allegedly showing everything except the gasket, and then looks to Chang to support an argument that it would, allegedly, have been obvious to modify Crawford to add the gasket of Chang. In that regard, Examiner argues that the Chang gasket is to prevent backflow along the needle and to wipe blood therefrom as the needle is withdrawn, and so one of ordinary skill in the art would want those same advantages in Crawford and would obtain them by adding the Chang gasket. Applicant respectfully submits that Examiner is in error.

Crawford already stops proximal movement of the needle when the enlarged section at the crimp 26 impacts against the back wall at opening 20 thereof. Hence, there is already a structure to stop the pull-out of the needle. Why, then, would someone also add the gasket which, in the claimed invention, is for stopping the proximal pull-out of the needle? That would seem to be superfluous, extra structure with no benefit in the device of Crawford. It is hardly fair to conclude that the addition of superfluous structure would have been obvious. And that is especially so in the circumstances here where there is no reason to add the gasket, contrary to Examiner's arguments.

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<sup>2</sup> This rejection is rather surprising, and disappointing, to Applicant at this late stage. This case has been pending since 2001 (as a divisional of a case filed in 1999), has been the subject of some six Official Actions and responses, and one appeal brief, all at great cost to Applicant's assignee. Yet, Crawford and Chang have been of-record all that time (as evidenced by Examiner checking them off as having been considered in the first Official Action in this case) without the Office asserting them in combination as a rejection.

In that regard, the tip protector design of Crawford leaves a large portion of the needle shaft exposed between the catheter hub and the back-end of the housing, such as along the clip thereof. In that context, "backflow" along the needle would not be prevented by a gasket positioned to stop proximal withdrawal of the needle, so that supposed goal cited by Examiner as motivation would not be met in any event.

Further, even Chang acknowledges that blood might leak past his gasket, such that Examiner's suppositions about that gasket are not entirely accurate. Rather, in Chang, blood leakage is simply not considered a problem because Chang includes a tether in the form of a sleeve enveloping the needle shaft. Thus, any blood leakage is along a shaft that is enclosed within a sleeve, such that it is not cause for concern. See Col. 15, ll. 10-18. But in the Crawford design, the needle shaft is exposed. Hence, the leakage that Chang can tolerate is no longer readily tolerated when the gasket is carried over to Crawford. Based directly on what Chang says of his own gasket, it is clear that the addition of that gasket to Crawford would not solve the issue Examiner says Chang solves.

Under the circumstances, it is respectfully submitted that the rejections based on the combination of Crawford and Chang are in error and should be withdrawn.

### **Conclusion**

In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, a formal Notice of Allowance is respectfully solicited. In the event that any issues remain outstanding or if Examiner is of the view that a reasonable amendment to the claims may be necessary to comport with the foregoing remarks, given the years this case has been pending, Examiner is invited, and encouraged, to contact

undersigned counsel in an effort to resolve any such efforts and to expedite prosecution of this application to conclusion.

No fee is considered due with this paper. If any fee is due or is not otherwise properly paid, the Commissioner is authorized to charge any such fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,  
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